UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

JULIA GORICKI, Plaintiff, vs. ANGIODYNAMICS, INC., & NAVILYST MEDICAL, INC., Defendants.	Case No.: 3:25-cv-00251-MGL **COMPLAINT FOR DAMAGES** **(1) NEGLIGENCE** **(2) FAILURE TO WARN** **(3) DESIGN DEFECT** **(4) BREACH OF IMPLIED WARRANTY** **(5) BREACH OF EXPRESS WARRANTY** **(6) FRAUDULENT CONCEALMENT** **(7) SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT (SCUTPA)** **DEMAND FOR JURY TRIAL**

COMES NOW the Plaintiff, Julia Goricki, (hereinafter "Plaintiff"), by and through her undersigned counsel, and brings this Complaint against AngioDynamics, Inc., and Navilyst Medical, Inc., (collectively, the "Defendants"), and alleges as follows:

1. There is an action for damages arising out of failures relating to Defendants' design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying, and/or selling the defective implantable vascular access device sold under the trade name of SmartPort Power Injectable Port (hereinafter "SmartPort" or "Defective Device").

PARTIES

2. At all times material, Plaintiff, Julia Goricki is an adult resident and citizen of Lexington County, South Carolina, and claims damages as set forth below.

3. Defendant AngioDynamics, Inc. ("AngioDynamics") is a Delaware corporation with its principal place of business located in Latham, New York. AngioDynamics is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing,

supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the SmartPort.

4. Defendant Navilyst Medical, Inc. ("Navilyst") is a Delaware corporation with its principal place of business located in Marlborough, Massachusetts. Navilyst conducts business throughout the United States, including the State of South Carolina, and is a wholly owned subsidiary of AngioDynamics. Navilyst is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the SmartPort.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and cost.

6. Venue is proper in this Court pursuant to 28 U.S.C. §1391 by virtue of the facts that (a) a substantial part of the events or omissions giving rise to the claims occurred in the District and (b) Defendants' products are produced, sold to, and consumed by individuals in the State of South Carolina, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

7. Defendants have and continue to conduct substantial business in the District of South Carolina, distribute vascular access products in this District, receive substantial compensation and profits from sales of vascular access products in this District, and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

8. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants because Defendants are present in the State of South Carolina, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

PRODUCT BACKGROUND

9. In or about 2007, a company called Rita Medical Systems, Inc. received clearance via the 510(k) Premarket Notification Program from the Food and Drug Administration (FDA) to market and sell a product called Vortex® CT Port Access System.

10. Around the same time, AngioDynamics completed the acquisition of the assets and liabilities of Rita Medical Systems, Inc. and rebranded the subject product as SmartPort.

11. Defendants' Vascular Access Devices were designed, patented, manufactured, labeled, marketed, sold, and distributed by the Defendants at all relevant times herein.

12. SmartPort is one of several varieties of port/catheter systems that has been designed, manufactured, marketed, and sold by Defendants.

13. According to Defendants, the SmartPort is a totally implantable vascular access device designed to provide repeated access to the vascular system for the delivery of medication, intravenous fluids, parenteral nutrition solutions, and blood products.

14. The intended purpose of the SmartPort is to make it easier to deliver medications directly into the patient's bloodstream. The device is surgically placed completely under the skin and left implanted.

15. The SmartPort is a system consisting of two primary components: an injection port and a polyurethane catheter which includes additives intended to make it radiopaque.

16. The injection port has a raised center, or "septum," where the needle is inserted for delivery of the medication. The medication is carried from the port into the bloodstream through a small, flexible tube, called a catheter, that is inserted into a blood vessel.

17. The SmartPort is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

18. The product's catheter is comprised of a polymeric mixture of polyurethane and a barium sulfate radiopacity agent.

19. Barium sulfate is known to contribute to reduction of the mechanical integrity of polyurethane in vivo as the particles of barium sulfate dissociate from the surface of the catheter over time, leaving microfractures and other alterations of the polymeric structure and degrading the mechanical properties of the polyurethane.

20. Researchers have shown that catheter surface degradation in products featuring a radiopaque barium sulfate stripe is concentrated at the locus of the stripe.[1]

21. The design of the product at issue in this case includes a catheter with a stripe containing a stripe with a higher concentration of barium sulfate than the rest of the catheter.

22. According to relevant medical literature, such design is proven to have a higher rate of fracture and infection than catheters without the barium-loaded stripe.

23. The mechanical integrity of a barium sulfate-impregnated polyurethane is affected by the concentration of barium sulfate as well as the heterogeneity of the modified polymer.

24. Upon information and belief, Defendants' manufacturing process in designing and constructing the catheter implanted in Plaintiff involved too high a concentration of barium sulfate

[1] See Hecker JF, Scandrett LA. Roughness and thrombogenicity of the outer surfaces of intravascular catheters. *J Biomed Mater Res.* 1985;19(4):381-395. doi:10.1002/jbm.820190404

particles for the polymer formulation, leading to improperly high viscosity of the admixed polyurethane before polymerization and causing improper mixing of barium sulfate particles within the polymer matrix.

25. This defect in the manufacturing process led to a heterogeneous modified polymer which led to an irregular catheter surface replete with fissure, pits and cracks as well as sections of the catheter lumen which contain more than 30% barium sulfate by weight, reducing the catheter strength at those loci.

26. The roughened catheter surface leads to the collection and proliferation of fibrinous blood products, thereby drastically increasing the risk of biofilm, infection, and sepsis.

27. Although the surface degradation and resultant mechanical failure can be reduced or avoided with design modifications (e.g., using a higher grade radiopacity compound and/or encapsulating the admixed polymer within polyurethane), Defendants elected not to incorporate those design elements into the SmartPort.

28. At all times relevant, Defendants misrepresented the safety of the SmartPort system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the SmartPort system as safe and effective device to be surgically implanted to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products.

29. At all times relevant to this action, Defendants knew and had reason to know, that the SmartPort was not safe for the patients for whom they were prescribed and implanted, because once implanted the device was prone to fracturing, perforating internal vasculature, and otherwise malfunctioning.

30. At all times relevant to this action, Defendants knew and had reason to know that

patients implanted with a SmartPort port had an increased risk of suffering life threatening injuries, including but not limited to: death; infection; hemorrhage; cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart); cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the defective device.

31. Soon after the SmartPort was introduced to market, which was years before Plaintiff was implanted with her device, Defendants began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the SmartPort was fracturing post-implantation and that fractured pieces were migrating throughout the human body, including to the heart and lungs. Defendants also received large numbers of AERs reporting that the SmartPort was found to have perforated internal vasculature. These failures were often associated with reports of severe patient injuries such as:

a. hemorrhage.

b. infection/sepsis;

c. cardia/pericardial tamponade;

d. cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. perforations of tissue, vessels and organs; and

f. upon information and belief, even death.

32. In addition to the large number of AERs which were known to Defendants and reflected in publicly accessible databases, there are many recorded device failures and/or injuries related to the Defendants' implantable port products which were concealed from medical professionals and patients through submission to the FDA's controversial Alternative Summary Reporting ("ASR") program.

33. The FDA halted the ASR program after its existence was exposed by a multi-part investigative piece, prompting a widespread outcry from medical professionals and patient advocacy groups.[2]

34. Prior to the discontinuation of the ASR program, Defendants reported numerous episodes of failures of their implanted port/catheter products – including numerous episodes of catheter infection – under the ASR exemption, thereby concealing them from physicians and patients.

35. Defendants were aware or should have been aware that SmartPort had a substantially higher failure rate than other similar products on the market, yet Defendants failed to warn consumers of this fact.

36. Defendants also intentionally concealed the severity of complications caused by SmartPort and the likelihood of these events occurring.

37. Rather than alter the design of the SmartPort to make it safer or adequately warn physicians of the dangers associated with the SmartPort, Defendants continued to actively and aggressively market the SmartPort as safe, despite their knowledge of numerous reports of catheter infection and associated injuries.

38. Moreover, Defendants concealed—and continue to conceal—their knowledge of the Smart Port's dangerous propensity to precipitate infection. Defendants further concealed their knowledge that the catheter design caused these failures and that these failures cause serious injuries.

39. The conduct of Defendants, as alleged in the Complaint, constitutes willful, wanton,

---

[2] Christina Jewett, *Hidden Harm: Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, Kaiser Health News (Mar. 2019)

gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff. Defendants had actual knowledge of the dangers presented by the SmartPort System, yet consciously failed to act reasonably to:

a. Adequately inform or warn Plaintiff, her prescribing physicians, or the public at large of these dangers;

b. Establish and maintain an adequate quality and post-market surveillance system; or

c. Recall the SmartPort System from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO JULIA GORICKI

40. On or about February 13, 2020, Plaintiff underwent placement of the AngioDynamics SmartPort Power Injectable Port, reference number H965451030, lot number 145069000. The device was implanted by Katherine T. Ostapoff, M.D., at Lexington Medical Center in Lexington County, South Carolina.

41. Defendant, directly or through their agents, apparent agents, servants, or employees designed, manufactured, marketed, advertised, distributed and sold the SmartPort that was implanted in Plaintiff.

42. Defendant manufactured, sold, and/or distributed the SmartPort to Plaintiff, through her doctors, to be used for delivery of chemotherapy.

43. On or about April 16, 2020, Plaintiff presented herself to Lexington Medical Center in Lexington County, South Carolina where it was determined she was suffering from port thrombosis and her port was subsequently removed and replaced the same day with another AngioDynamics SmartPort Power Injectable Port. On or about December 16, 2021, Plaintiff presented herself again to the Lexington Medical Center in Lexington County, South Carolina

where she again had the port removed and replaced with another AngioDynamics SmartPort Power Injectable Port due to port thrombosis. On or about January 14, 2022, Plaintiff presented herself to the Lexington Medical Center in Lexington County, South Carolina where she had the port removed due to port thrombosis.

44. At all times, SmartPort was utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use and created procedures for implanting the product.

45. The SmartPort implanted in Plaintiff was in the same or substantially similar condition as when it left the possession of Defendants and in the condition directed by and expected by Defendants.

46. Plaintiff and her physicians foreseeably used and implanted the SmartPort and did not misuse or alter the SmartPort in an unforeseeable manner.

47. Defendants advertised, promoted, marketed, sold, and distributed the SmartPort as a safe medical device when Defendant knew or should have known the SmartPort was not safe for its intended purposes and that the product could cause serious medical problems.

48. Defendants had sole access to material facts concerning the defective nature of the SmartPort product and its propensity to cause serious and dangerous side effects.

49. In reliance on Defendants' representations, Plaintiff's doctor was induced to and did use the SmartPort.

50. As a result of having the SmartPort implanted, Plaintiff has experienced significant pain and suffering, has undergone additional surgeries, and has suffered financial or economic loss, including, but to limited to, obligations for medical services and expenses.

51. Defendants' SmartPort was marketed to the medical community and to patients as a safe, effective, reliable, medical devices implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, and as safer and more effective as compared to the traditional products and procedures for treatment and other competing Vascular Access Devices.

52. The Defendants have marketed and sold the Defendants' SmartPort to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and/or group purchasing organizations, and include a provision of valuable consideration and benefits to the aforementioned.

53. The injuries, conditions, and complications suffered due to Defendants' SmartPort include but are not limited to infection; necrosis; fracture and leakage; blood clots; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforations of tissue, vessels and organs; and even death.

54. Defendants were negligent toward Plaintiff in the following respects:

a. Defendant failed to design and establish a safe, effective procedure for removal of SmartPort; therefore, in the event of a failure, injury, or complications it is difficult to safely remove SmartPort.

b. Defendants provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using SmartPort for the purpose of increasing their sales. By so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including the Plaintiff.

55. The SmartPort was utilized and implanted in a manner foreseeable to Defendants.

56. The SmartPort implanted into Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants and in the condition directed by the Defendants.

57. At the time of her operation, Plaintiff was not informed of, and had no knowledge of the complaints, known complications, and risks associated with SmartPort, including but not limited to the extent of seriousness of the danger of infection.

58. Plaintiff was never informed by Defendants of the defective and dangerous nature of the SmartPort.

59. At the time of her implant, neither Plaintiff nor Plaintiff's physicians were aware of the defective and dangerous condition of SmartPort.

60. As a result of the Defendants' actions and inactions, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

FIRST CAUSE OF ACTION

NEGLIGENCE

(Against Defendants AngioDynamics and Navilyst)

61. Plaintiff incorporates paragraphs 1 through 60 as if set out fully herein.

62. The Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, selling, and conducting post-market surveillance of the SmartPort.

63. The Defendants failed to exercise due care under the circumstances and therefore breached this duty by:

a. Failing to properly and thoroughly test the SmartPort before releasing the device to market, and/or failing to implement feasible safety improvements;

b. Failing to properly and thoroughly analyze the data resulting from any pre-market testing of the SmartPort;

c. Failing to conduct sufficient post-market testing and surveillance of the SmartPort;

d. Failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the SmartPort;

e. Designing, manufacturing, marketing, advertising, distributing, and selling the SmartPort to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the SmartPort and without proper instruction to avoid the harm which could foreseeably occur as a result of using the device;

f. Failing to exercise due care when advertising and promoting the SmartPort; and

g. Negligently continuing to manufacture, market, advertise, and distribute the SmartPort after Defendants knew or should have known of its adverse effects.

64. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

65. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted grossly negligent, fraudulently, and with malice.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Against Defendants AngioDynamics and Navilyst)

66. Plaintiff incorporates paragraphs 1 through 65 as if set out fully herein..

67. Defendants designed, set specifications, manufactured, assembled, processed, marketed, labeled, distributed, and sold the SmartPort, including the one implanted in Plaintiff, into the stream of commerce and in the course of the same, directly advertised and marketed the device to consumers or persons responsible for consumers, and therefore had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device.

68. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, the device was defective and presented a substantial danger to users of the product when put to its intended and reasonably anticipated use, namely as an implanted port/catheter system to administer the medications. Defendants failed to adequately warn of the device's known or reasonably scientifically knowable dangerous propensities and further failed to adequately provide instructions on the safe and proper use of the device.

69. Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the SmartPort that was implanted into Plaintiff that the SmartPort posed a significant and higher risk than other similar devices of device failure and resulting serious injuries.

70. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the SmartPort; no reasonable health care provider, including Plaintiff's, and no reasonable patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers or the consumers of the device.

71. The warnings, labels, and instructions provided by the Defendants at all times relevant to this action, are and were inaccurate, intentionally misleading, and misinformed and misrepresented the risks and benefits and lack of safety and efficacy associated with the device.

72. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

73. The SmartPort, which was designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold into the stream of commerce by Defendants, was defective at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

74. When Plaintiff was implanted with the device, Defendants failed to provide adequate warnings, instructions, or labels regarding the severity and extent of health risks posed by the device, as discussed herein.

75. Defendants intentionally underreported the number and nature of adverse events associated with infection, fracture and migration of the devices to Plaintiff's health care providers, as well as the FDA.

76. Upon information and belief, neither Plaintiff nor her health care providers knew of the substantial danger associated with the intended and foreseeable use of the device as described herein.

77. Plaintiff and her health care providers used the SmartPort in a normal, customary, intended, and foreseeable manner, namely as a surgically placed device used to make it easier to deliver medications directly into the patient's bloodstream.

78. Upon information and belief, the defective and dangerous condition of the device, including the one implanted into Plaintiff, existed at the time they were manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold by Defendants to distributors and/or healthcare professionals or organizations.

79. Upon information and belief, the device implanted in Plaintiff was in the same

condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

80. Defendants' lack of sufficient warning and/or instructions was the direct and proximate cause of Plaintiff's serious physical injuries, and economic damages in an amount to be determined at trial. Had Defendants provided adequate warnings, Plaintiff and her physicians would not have used the device.

81. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

82. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted grossly negligent, fraudulently, and with malice.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(Against Defendants AngioDynamics and Navilyst)

83. Plaintiff incorporates paragraphs 1 through 82 as if set out fully herein.

84. Defendants supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the SmartPort implanted into Plaintiff.

85. The SmartPort implanted in the Plaintiff was not reasonably safe for its intended use and was defective with respect to its design.

86. The SmartPort was in a defective condition and was defective in its design in that when it left the possession and control of Defendants, it was not safe for its anticipated use and safer, more reasonable alternative designs existed that could have been utilized by Defendants.

87. The SmartPort was unreasonably dangerous to the user or consumer, taking into consideration the utility of said product and the risks involved in its use. The foreseeable risks

associated with the design of the product were more dangerous than a reasonably prudent consumer such as Plaintiff and/or her physicians would expect when the product was used for its normal and intended purpose.

88. SmartPort was expected to and did reach the consumer without substantial change in the condition in which it was supplied, distributed, sold and/or otherwise placed into the stream of commerce.

89. A reasonably prudent medical device manufacturer would have recognized the defective design of the SmartPort and not placed it into the stream of commerce.

90. The design defects in the SmartPort were not known, knowable and/or reasonably apparent to Plaintiff and/or her physician or discoverable upon any reasonable examination.

91. The SmartPort was used and implanted in the manner in which it was intended to be used and implanted by Defendants pursuant to the instructions for use and the product specifications provided by Defendants.

92. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

93. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted grossly negligently, fraudulently, and with malice.

FOURTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

(Against Defendants AngioDynamics and Navilyst)

94. Plaintiff incorporates paragraphs 1 through 93 as if set out fully herein.

95. Defendants impliedly warranted that the SmartPort was merchantable and fit for the ordinary purposes for which it was intended.

96. When the SmartPort was implanted in the Plaintiff, it was being used for the ordinary purposes for which it was intended.

97. The Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have the SmartPort implanted in her.

98. Privity exists between Plaintiff and the Defendants because Plaintiff's physicians acted as Plaintiff's purchasing agents in the subject transaction and/or because Plaintiff was a third-party beneficiary of the subject contract.

99. Plaintiff was the intended consumer of the device when Defendants made the warranties set forth herein, and such warranties were made to benefit Plaintiff as a patient and consumer.

100. Defendants breached these implied warranties of merchantability because the SmartPort implanted in Plaintiff was neither merchantable nor suited for its intended uses as warranted in that the device varied from its intended specifications, which included, but were not limited to, variances in the following respects:

a. Defendants' manufacturing process in constructing the catheter of the SmartPort implanted in Plaintiff involved too high of a concentration of barium sulfate particles for the polymer formulation, which led to improperly high viscosity of the admixed polyurethane before polymerization and causing improper mixing of barium sulfate particles within the polymer matrix;

b. Defendants knew or should have known barium sulfate is known to contribute to a reduction in the mechanical integrity of the polyurethane in its product, the SmartPort, as the barium sulfate particles dissociate from the surface of the

catheter over time; and

c. These defects led to a heterogenous modified polymer that included microfractures and weakened areas at the location of the higher barium sulfate concentration that ultimately led to the collection and proliferation of blood products, thereby drastically increasing the risk of biofilm, infection, and sepsis.

101. Defendants' breaches of their implied warranties resulted in the implantation of unreasonably dangerous and defective product, the SmartPort, into Plaintiff's body, placing said Plaintiff's health and safety in jeopardy.

102. The SmartPort was sold to the Plaintiff's health care providers for implantation in patients, such as Plaintiff.

103. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

104. Upon information and belief, Plaintiff's healthcare providers sent notice to Defendants of the adverse event that occurred to Plaintiff and thus, the nonconformity of the SmartPort, within a reasonable period of time following discovery of the breach of warranty and before suit was filed.

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(Against Defendants AngioDynamics and Navilyst)

105. Plaintiff incorporates paragraphs 1 through 104 as if set out fully herein.

106. Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the SmartPort was safe and fit for use by consumers, was of merchantable quality, did not produce

dangerous side effects, and was adequately tested and fit for its intended use.

107. The SmartPort does not conform to the Defendants' express representations because it is not reasonably safe, has numerous serious side effects, and causes severe and permanent injury.

108. Defendants further breached express representations and warranties made to Plaintiff, her physicians and healthcare providers with respect to the SmartPort implanted in Plaintiff in the following respects:

a. Defendant represented to Plaintiff and her physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' SmartPort was safe, meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using SmartPort;

b. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' SmartPort was as safe and/or safer than other alternative procedures and devices then on the market, but fraudulently concealed information that demonstrated that SmartPort was not safer than alternative therapies and products available on the market; and

c. Defendants represented to Plaintiff and her physicians and healthcare providers that the SmartPort was more efficacious than other alternative procedures, therapies and/or devices. Meanwhile, Defendants fraudulently concealed information regarding the true efficacy of SmartPort.

109. At all relevant times, the SmartPort did not perform as safely as an ordinary

consumer would expect, when used as intended or in a reasonably foreseeable manner.

110. Plaintiff, her physicians, and the medical community reasonably relied upon the Defendants' express warranties for the SmartPort.

111. Privity exists between Plaintiff and the Defendants because Plaintiff's physicians acted as Plaintiff's purchasing agents in the subject transaction and/or because Plaintiff was a third-party beneficiary of the subject contract.

112. Plaintiff was the intended consumer of the device when Defendant made the warranties set forth herein, and such warranties were made to benefit Plaintiff as a patient and consumer.

113. Plaintiff was intended consumer of the SmartPort when Defendants made the warranties set forth herein, and such warranties were made to benefit Plaintiff as a patient and consumer.

114. At all relevant times, the SmartPort was used on Plaintiff by Plaintiff's physicians for the purpose and in the manner intended by Defendants.

115. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

116. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

117. Upon information and belief, Plaintiff's healthcare providers sent notice to Defendants of the adverse event that occurred to Plaintiff and thus, the nonconformity of the SmartPort, within a reasonable period of time following discovery of the breach of warranty and before suit was filed.

SIXTH CAUSE OF ACTION

FRAUDULENT CONCEALMENT

(Against Defendants AngioDynamics and Navilyst)

118. Plaintiff incorporates paragraphs 1 through 117 as if set out fully herein.

119. Defendants made false statements and representations to Plaintiff and her healthcare providers concerning the SmartPort product implanted in Plaintiff.

120. Defendants engaged in and fraudulently concealed information with respect to the SmartPort in the following respects:

a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the SmartPort was safe and fraudulently withheld and concealed information about the substantial risks of using the SmartPort, including but not limited to, its heightened propensity to precipitate infection, and cause complications;

b. Defendants represented that the SmartPort was safer than other alternative systems and fraudulently concealed information which demonstrated that the SmartPort was not safer than alternatives available on the market;

c. Defendants concealed that they knew these devices were fracturing and migrating from causes other than the manner in which the implanting physician implanted the device; and

d. That frequency of these failures and the severity of injuries were substantially worse than had been reported.

121. Defendants had knowledge that the representations they made concerning SmartPort, as stated above, were false.

122. Defendants had sole access to material facts concerning the dangers and unreasonable risks of SmartPort.

123. The concealment of information by the Defendants about the risks of SmartPort was intentional.

124. The concealment of information and the misrepresentations about the SmartPort was made by the Defendants with the intent that Plaintiff's health care providers and Plaintiff rely upon them.

125. Plaintiff and her physicians relied upon the representations and were unaware of the substantial risks of the SmartPort which the Defendants concealed from the public, including Plaintiff and her physicians.

126. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has been injured and has sustained economic and non-economic damages, both in the past and future, including for pain and suffering and medical expenses.

127. The Defendants acted with oppression, fraud, and malice towards Plaintiff.

128. Had Defendants not concealed this information, neither Plaintiff's nor her health care providers would have consented to using the device in Plaintiff.

SEVENTH CAUSE OF ACTION
SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT
(SCUTPA)
(Against Defendants AngioDynamics and Navilyst)

129. Plaintiff incorporates paragraphs 1 through 128 as if set out fully herein.

130. Plaintiff, a consumer, purchased the SmartPort, and the product was intended for Plaintiff's personal use.

131. The acts and practices engaged in by Defendants as outlined above constitute unlawful, unfair, deceptive and/or fraudulent business practices in violation of the South Carolina

Unfair Trade Practices Act. SC Code § 39-5-20 (2023).

132. Defendants engaged in unlawful practices including deception, false promises, misrepresentation, and/or the concealment, suppression, or omission of material facts in connection with the sale, distribution, and/or advertisement of the SmartPort in violation of SC Code § 39-5-20 (2023).

133. Defendants further engaged in unfair, unconscionable, deceptive, deliberately misleading, false, and/or fraudulent and/or deceptive acts and practices, all in violation of the SC Code § 39-5-20 (2023), and as further described herein, including, but not limited to, misrepresenting that the SmartPort was reasonably safe for use and failing to adequately disclose the substantial risk of infection, and harm the product entailed given the large number of adverse events Defendants knew or should have been aware of but did not adequately disclose to Plaintiff.

134. Defendants' practices were likely to mislead consumers who acted reasonably to their detriment in purchasing the product based on Defendants' representations that it was reasonably safe for use when it in fact was not and had a higher risk of infection due to its defective design.

135. Defendants intended for Plaintiff, Plaintiff's physicians, and other consumers to rely on their deceptive practices and representations in order to continue selling and manufacturing SmartPort.

136. As a result of Defendants' conduct, Plaintiffs suffered economic damages in that the product purchased was misrepresented to be reasonably safe for use and was worth far less than the product Plaintiff thought she had purchased had Defendants' representations been true.

PRAYER

WHEREFORE, Plaintiff prays for judgment against each of the Defendants as follows:

a. Judgment be entered against all Defendant on all causes of action of this Complaint;

b. Plaintiff be awarded her full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiff be awarded general damages according to proof at the time of trial;

d. Plaintiff be awarded damages, including past, present, and future, medical expenses according to proof at the time of trial;

e. Plaintiff be awarded actual damages in connection with Plaintiff's claims under the South Carolina Unfair Trade Practices Act. SC Code § 39-5-20 (2023).

f. Awarding pre-judgment and post-judgment interest to the Plaintiff;

g. Awarding the costs and the expenses of this litigation to the Plaintiff.

h. For such other and further relief as the court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

LAW OFFICE OF KENNETH E. BERGER, LLC

/s/Bradley L. Lanford
blanford@bergerlawsc.com
Federal Bar No.: 9371
5205 Forest Drive
Columbia, SC 29206
(803) 790-2800 (phone)
(803) 790-2870 (fax)
Attorney for Plaintiff

January 14, 2025
Columbia, South Carolina